UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,136	12/01/2006	David Teh-Wei Chou	MER 05-3176	4881
Dr. Judy Jareck	7590 05/20/200 i-Black	EXAMINER		
Merial Limited			KLINKEL, KORTNEY L	
3239 Satellite Boulevard Duluth, GA 30096			ART UNIT	PAPER NUMBER
			1611	
			MAIL DATE	DELIVERY MODE
			05/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/570,136	CHOU ET AL.				
Office Action Summary	Examiner	Art Unit				
	Kortney L. Klinkel	1611				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 01 Ap	oril 2009.					
·= · · · · · · · · · · · · · · · · · ·	action is non-final.					
<i>;</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-6, 9-12, and 14-21</u> is/are pending in the application.						
4a) Of the above claim(s) <u>1-6,11 and 14-17</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>9,10,12 and 18-21</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign	priority under 35 LLS C & 110(a)	(d) or (f)				
a) ☐ All b) ☐ Some * c) ☐ None of:	priority under 35 0.5.6. § 119(a)	-(u) Or (i).				
a)						
		on No				
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other:						

DETAILED ACTION

Status

Acknowledgement is made of Applicant's claim amendments and remarks/arguments filed 4/1/2009

Claim 13 was canceled. Claims 18-21 were newly added. Claims 9-10 and 12 were amended. Claims 1-6 and 9-12, and 14-21 are pending in the instant Office action. Claims 1-6, 11 and 14-17 remain withdrawn for being directed to non-elected subject matter.

Claims 9-10, 12 and 18-21 are under consideration in the instant Office action to the extent that they read on a compound of formula (I) wherein W is C-halogen.

Withdrawn Claim Objections

The objection to claims 9-10 and 12-13 for being dependent on the composition of withdrawn claims is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 21, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations "a dog or a cat" following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Application/Control Number: 10/570,136 Page 4

Art Unit: 1611

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-10, 12 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 98/28279, as per Applicants' IDS) and in further view of Ribeill et al. (WO 00/35884, as per Applicants' IDS).

Manning teaches 1-arylpyrazoles of the following general formula and their use as pesticides (page 2, also claims 1-2, 4, 9-10, 13, and 16).

$$R_5S(O)_n$$
 NH_2
 R_1
 R_2
 R_3

Manning's R_1 , which corresponds to the instant R^2 can be H or halogen. Manning's R_2 and R_4 can be hydrogen, *inter alia* as in the instant compounds. Manning's R_3 , which corresponds to the instant R^3 can be -CF₃, and -OCF₃ *inter alia*. Manning's M, which corresponds to the instant W, can be -C-Cl as in the instant compounds. Manning teaches CSNH₂ in the instant R^1 position for all of the compounds. Manning's Z, which corresponds to the instant R^1 -QSition for all of the compounds. Manning's Z, which wherein each of R_6 , R_7 and R_8 are identical or different and are selected from alkyl-S(O)_p- or alkenyl optionally substituted by one or more R_9 wherein R_9 is R_{10} S(O)_q-, haloalkoxy, alkoxy, *inter alia*, and R_{10} is lower alkyl or lower haloalkyl. Manning's R_5 , which corresponds to the instant R^6 CFX-, can be haloalkyl, *inter alia*. As just described,

the general structure taught by Manning encompasses the general class of compounds encompassed in the instant claims.

Manning further teaches a method for the control of pests in or on an animal which comprises administering to said animal a pesticidally effective amount of a compound of formula (I) or salt thereof (claim 21).

Manning fails to teach a specific example wherein R_5 is haloalkyl or where R_2 is a tertiary amine as required by the newly amended claims of 4/1/2009. But as discussed above, the specific combination of features claimed is disclosed within the broad generic ranges taught by Manning, but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise

teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected R_5 (corresponding to instant R^6CFX) to be haloalkyl from within the disclosure of Manning, and Z to be tertiary amino, to arrive at the instant compounds "yielding no more than one would expect from such an arrangement". One of ordinary skill in the art would be imbued with a reasonable expectation that 1-arylpyrazoles of the instant claims having a tertiary amine functionally as well as a haloalkyl group attached to $-S(O)_n$ would function as a pesticide.

That being said, the teachings of Ribeill provide addition motivation for arriving at the instantly claimed compounds.

Ribeill teaches 1-arylpyrazoles of the following general formula and their use as pesticides (pages 2-3, also claim 1)

Ribeill's R_1 , which corresponds to the instant R^1 , can be $C(S)NH_2$, as necessitated by the claims. Ribeill's R_{11} , which corresponds to the instant R^2 can be hydrogen or halogen, *inter alia*. Ribeill's R_{13} , which corresponds to the instant R^3 , can be halogen, haloalkyl, haloalkoxy, $-S(O)_qCF_3$ and $-SF_5$. Ribeill's X, which corresponds to the instant W can be C-halogen. Ribeill's R_4 , which corresponds to the instant $N-(R^4)-A-S(O)_mR^5$, can be $-N=C(R_5)-Z-R_6$ wherein Z can be S, as necessitated by the instant claims. Ribeill's R_2 , which corresponds to the instant $R^6CFX-S(O)_n$ can be $S(O)_nR_3$ wherein R_3 is haloalkyl. All of the compounds in Tables 1-3 contain compounds wherein R_2 meets the limitations of the instant claims. As just described, the general structure taught by Ribeill encompasses the general class of compounds encompassed in the instant claims and differ only in the R_4 position. The compounds of Ribeill contain an imine nitrogen, or the oxidized form of an amine in this position.

Ribeill further teaches a method for the control of pests in or on an animal which comprises administering to said animal a pesticidally effective amount of a compound of formula (I) or salt thereof (claim 1).

Accordingly, it would have also been obvious to one of ordinary skill in the art, at the time of the instant invention to arrive at the instant method for controlling pests with the instant 1-arylpyrazoles based on the teachings of Manning in view of Ribeill with a reasonable expectation for success. One would have been motivated to do so because Manning and Ribeill teach a finite number of 1-arylpyrazoles compounds which are useful as pesticides and as pesticides to control pests in or on animals which is the same utility as claimed. The genus of compounds discussed by Manning, again,

encompasses the set of compounds currently claimed. It is generally accepted that structurally similar compounds will show similar behavior. Accordingly, the skilled artisan would have been motivated to synthesize and test compounds having the required $R^6CFX-S(O)_n$ and $N-(R^4)-A-S(O)_mR^5$ functionality as compounds with identical cores having these functionalities have shown excellent efficacy as pesticides in the prior art.

Applicant's data in the specification has been considered. Of the 9 compounds tested (compounds 1-1 through 1-9) for the control of cat fleas, all gave at least 80% control at a concentration of 5 ppm or less. Compounds 1-1 through 1-9 all have $R^1 = CSNH_2$, W = C-CI, $R^2 = CI$, $R^3 = CF_3$ and $R^4 = Me$, $A = CH_2CH_2$. The compounds have different $R^5S(O)_m$ and $R^6CFX-S(O)_n$. This evidence suggests that the core of the molecule is all that is necessary for functionality, since the system can tolerate changes in the $R^5S(O)_m$ and $R^6CFX-S(O)_n$ positions. Furthermore, applicants' data shows no unexpected results. Of the roughly 100 structurally similar compounds tested by Ribeill, they showed *in vivo* control of fleas in cats and dogs with superior results to fipronil, a known 1-arylpyrazole shown in the art to control fleas (page 42).

Response to Arguments

Applicant's arguments filed 4/1/2009 in response to the rejection of claims have been fully considered, but are moot in view of the new grounds of rejection above which take into consideration the narrower claim scope. However, the Examiner will address any issues relevant to the teachings of Manning and Ribeill.

Applicant argues that the references relied upon by the Office do not render Applicant's invention obvious. More specifically, applicant argues that one skilled in the art would not be motivated to derive the presently claimed methods for controlling pests which comprise applying a pesticidally effective amount of a 5-substituted alkylaminopyrazole compound of formula (I) based on the teachings of Manning in view of Ribeill. Applicant argues that none of the compounds shown by Manning in Table 1 are tertiary 5-amino pyrazole derivatives as recited in the instant claims. This argument is not persuasive. Whereas it is true that none of the compounds shown in Table 1 of Manning are directed to a tertiary amine, tertiary amines are suggested from a finite number of possible combinations for the Z-group of Manning (see pages 2-3). The lack of a specific example precludes the teaching of Manning as being anticipatory of the instant invention. However, as discussed in the above rejection, it would have obvious to have selected R₅ (corresponding to instant R⁶CFX) to be haloalkyl from within the disclosure of Manning, and Z to be tertiary amino, to arrive at the instant compounds "yielding no more than one would expect from such an arrangement" since these functionalities are taught from a finite list of possible options. One of ordinary skill in the art would be imbued with a reasonable expectation that 1-arylpyrazoles of the instant claims having a tertiary amine functionally as well as a haloalkyl group attached to $-S(O)_n$ would function as a pesticide.

Applicant also argues that Manning does not relate to the activity of the described compounds against *Ctenocephalides felis* and therefore cannot render the instant claims obvious. This argument is not persuasive. It is noted that the features

upon which applicant relies (i.e., the control of Ctenocephalides felis) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, assuming arguendo that applicant's claims specified wherein the pests are Ctenocephalides felis, Manning at page 23, line 23 teaches that the general class of 1-aminopyrroles are effective against fleas. Furthermore, the teaching of Ribeill at page 42 show that the 1-aminopyrazoles are effective against fleas, specifically Ctenocephalides felis. Accordingly, because the teachings of both Manning and Rebeill make prima facie obvious the claimed compounds and both teach that they are effective against fleas, and more specifically Ctenocephalides felis, one of ordinary skill in the art would be imbued with the expectation that the instant compounds would also be effective against Ctenocephalides felis.

Applicant also argues that Ribeill does not relate to the administration of compounds of formula (I) at concentrations of 5 ppm or less. Again, applicant's claims are not directed to the administration of a concentration of 5ppm or less, so these arguments are not persuasive. Assuming arguendo that the claims did recite the administration of 5 ppm or less of the active compounds, the teachings of Manning in view of Rebeill would still render the instant methods obvious as applicant has failed to provide any unexpected results commensurate in the scope of the claimed invention. Furthermore, Ribeill teaches in the example spanning page 41 and 42 that 5 mg of active ingredient per kilogram of body weight was applied. It is well known in the art

that dosage amounts are dependent upon the subject's body mass. One would therefore tailor the administered amount to suite the subject. For example, one would likely apply a greater amount of active ingredient to a full grown Great Dane as compared to a kitten. Additionally, Manning teaches that the effective concentration of active ingredient ranges from 0.0001 ppm to about 20 ppm (p. 31).

In summary, applicant has not provided any evidence of unexpected results to rebut the *prima facie* case of obviousness presented herein.

Conclusion

Claims 9-10, 12 and 18-21 are rejected. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Application/Control Number: 10/570,136 Page 12

Art Unit: 1611

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-

5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/ Supervisory Patent Examiner, Art Unit 1611